UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,949	08/09/2001	Jan Zavada	D-0021.5C-1	9458

24988 7590 04/24/2006

LEONA L. LAUDER
235 MONTGOMERY STREET, SUITE 1026
SAN FRANCISCO, CA 94104-0332

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,949	ZAVADA ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-37,39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-37,39,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: ZAVADA ET AL

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/07/2006 has been entered.

2. The amendment filed 2/07/2006 is acknowledged and entered into the record. Accordingly, claims 1-30,38,40, and 43-44 are canceled without prejudice or disclaimer.

3. Claims 31-37,39, and 41-42 are pending and examined on the merits.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 31-32,34, 37,39, and 41 under 35 USC § 102(b) as being anticipated by Zavada *et al* (Int. J. Oncology 1997;10:857-863) is maintained for the reasons of record. Applicant argues that the cited reference does not anticipate the instantly claimed invention. Specifically, applicant argues that the language of the claims (i.e. "whose nucleotide sequence is selected from the group consisting of")

provides closed, not open language. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The use of the "selected from the group consisting of" language only provides closed language for the groups listed. However, proceeding such language, the claim recites the phrase "whose nucleotide sequence is" which for the purposes of this rejection has been interpreted as equivalent to comprising or open language. Therefore, the fusion protein of Zavada *et al* comprises a nucleotide sequence which at the very least would hybridizes to the sequence of SEQ ID No: 1. Although it is clear that the entire nucleotide sequence as provided by Zavada *et al* does not hybridize to the claimed sequence of SEQ ID No: 1 (because the GST fusion portion does not share homology with the sequence of SEQ ID No: 1), the sequence will nonetheless will hybridize because there is a significant portion that is identical to SEQ ID No: 1.

Applicant also contends that the sequence which hybridizes to SEQ ID No: 1 must have at least 80-90% sequence identify to SEQ ID No: 1 in order to hybridize. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, applicant argues that in order for sequences to hybridize to the claimed sequence of SEQ ID No: 1, those sequences must be at least 80-90% identical to SEQ ID No: 1, however, these limitations are not present in the claims and therefore not persuasive to rebut the anticipation rejection.

However, even assuming *arguendo*, that the claims recite that a sequence must be 80-90% identical to SEQ ID No: 1, the MN-GST fusion protein as disclosed by Zavada *et al,* would be 100% identical to SEQ ID No: 1, especially the MN portion of the fusion protein. Moreover, applicant has not indicated that the MN protein of Zavada *et al* is different from that of the instantly claimed SEQ ID No: 1 or would not hybridize, in part, to SEQ ID No: 1.

Applicant further argues that the nucleotide sequence of (ii) and (iii) are functionally defined in the claims because the MN protein or polypeptide comprises MN's cell adhesion site and that it be bound by the M75 antibody. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant's have not set forth any evidence to suggest that the N portion of the MN-GST fusion protein is any different from SEQ ID No: 1 as instantly claimed. Therefore, the fusion protein as disclosed by Zavada *et al* would comprise the cell adhesion site. Zavada *et al* also clearly indicates that the M75 antibody is capable of binding to the MN protein. Therefore, the functional limitations claimed have been clearly anticipated.

Applicant again reiterates arguments previously presented concerning the inoperative teachings of Zavada *et al* by providing additional information concerning the how the reference teaches away from the claimed invention. And states that the invention requires the identification of molecules that "do inhibit adhesion of cells to the MN protein." Applicant further provides reasons mhy the procedude perfomed by

Zavada *et al* are flawed. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The methods of the invention only require the identification of molecules, and does not require the specific determination of whether the molecule is capable of specifically inhibit adhesion of cell binding as being operative (i.e. block or not block), but only requires that the method be performed using the claimed components (i.e. sequence comprising SEQ ID No: 1 and a molecule -- (i.e. the molecule being screened). In other words, there is no active step that requires the specific identification of working embodiments (i.e. those that work), only that molecules be idenetified as to whether they bind or not bind. The fact that the experimentation was flawed and the details of why it did or didn't bind are irrelevant because the method as claimed was clearly performed by Zavada *et al*.

Therefore, the rejection of claims under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

6. The rejection of claims 31-32,34,37,39, and 41-42 under 35 USC § 103(a) as being obvious over Zavada *et al* is maintained for the reasons of record. Applicants' arguments are substantially similar to those presented and rebutted above. Applicant additionally argues that the reference teaches away from the claimed invention because of flawed technical errors. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant's arguments have already been addressed above. But to reiterate, the methods of the invention only require the identification of molecules, and does not require the specific determination of whether the molecule is capable of specifically inhibit adhesion of cell binding as being operative (i.e. block or not block), but only requires that the method be performed using the claimed components (i.e. sequence comprising SEQ ID No: 1 and a molecule -- (i.e. the molecule being screened). In other words, there is no active step that requires the specific identification of working embodiments (i.e. those that work), only that molecules be idenetified as to whether they bind or not bind. The fact that the experimentation was flawed and the details of why it did or didn't bind are irrelevant because the method as claimed was clearly performed by Zavada *et al.*

Therefore, the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

NEW REJECTIONS

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 31-37,39,41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case has only set forth a peptide sequence which consists of or comprises the sequence of

SEQ ID No: 50 or the sequence of 10 and 98-103, and therefore the written description is not commensurate in scope to the claims that read on a peptide sequence which consists of or comprises a sequence of SEQ ID No: 1, 10, or 98-103 as claimed. The following *written description* rejection is set forth herein.

The claims recite "an amino acid sequence" of any one of SEQ ID No: 50, 10, or 98-10 as part of the invention. This reads on a fragment as small as two amino acid found within the sequence of SEQ ID No: 50, 10, or 98-103. However, there does not appear to be an adequate written description in the specification as-filed that is representative of the fragment as small as two amino acid sequences derived from SEQ ID No: 50, 10, or 98-103, which is encompassed by the claimed peptide sequences. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice the broad genus of "an amino acid sequence" derived from either SEQ ID No: 50, 10, or 98-103. Neither has

Applicant provided a sufficient written description of any particular structure of "an amino acid sequence " derived from SEQ ID No: 50, 10, or 98-103. "[A]n amino acid sequence" encompasses *any* amino acid sequence, as small as 2 amino acids, found within SEQ ID No: 50, 10, or 98-103. Thus the genus of compounds encompassed by this phrase is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is also invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

It is noted that applicant may overcome this rejection by amending the claims to recite a peptide comprising "the amino acid sequence".

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
April 13, 2006

CHRISTOPHER YAEN
PATENT EXAMINER